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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,959	10/30/2003	Craig C. Hodges	00020.08CON	8482

37485 7590 07/03/2006

SWANSON & BRATSCUN, L.L.C  
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EXAMINER
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HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/696,959

Applicant(s)

HODGES ET AL.

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/21/06 has been entered.

Receipt is acknowledged of the Amendments and Remarks filed 04/21/06. No claims are cancelled and no new claims added. Accordingly claims 1-17 remain pending.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howell et al (5,743,251) in view of Wiedmann et al (5,747,001).

Howell et al teaches aerosols formed by supplying a material in liquid form to a tube and heating the tube such that the material volatizes and expands out of an open end of the tube. The volatized material combines with ambient air such that volatized

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material condenses to form the aerosol (see abstract). The aerosols have an average mass median particle diameter of less than 2 microns to facilitate deep lung penetration. The drug is delivered at a rate of above 1 mg/sec (see col. 2, lines 1-9). The device contains a thin platinum layer and an aluminum tube (see col. 3, lines 60-66). The thin film heater layer is deposited on the ceramic tube. The heater layer is preferably a thin platinum film having a thickness of less than 2 microns (col. 4, lines 12-20). The fluid is said to be fed at a rate of 1.5 mg/sec (col. 12, lines 33-36). Howell lacks disclosure on particles of less than 0.1 micron.

Wiedmann et al teaches an aerosol comprising droplets of an aqueous dispersion of nanoparticles (see abstract). The particles are preferably in a size of less than 400 nm. In some embodiments the particles are in a size of less than 100 nm (see col. 10, lines 28-38). Method of preparing the said nanoparticles are disclosed (col. 9).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the teachings of Howell on preparing particles of less than 2 microns for inhalation purposes, to have looked in the art for more specific and suitable particle sizes for pulmonary delivery of active agents as taught by Wiedmann et al with the reasonable expectations of successfully preparing more effective particles for fastest and most efficient delivery of active agents to the pulmonary system for local and systemic absorption.

### ***Double Patenting***

The nonstatutory double patenting rejections of U.S. Patent Nos. 6776978, 6716417, 6797259, 6740309, 6743415, 6737042, 6814955, 6805584, 6716415, 6803031, 6759029, 6737043, 6740308, 6740307, 6716416, 6783753, 6780400, 6780399, 6805853 and 6814954 are maintained.

The provisional nonstatutory double patenting rejections of copending Application Nos. 10/815527, 10/816492, 10/768220, 10/766574, 10/813721, 10/767115, 10/816567, 10/766279, 10/766641, 10/814998, 10/718982, 10/769157, 10/769197, 10/769051, 10/768205, 10/766647, 10/792013, 10/792012, 10/766634, 10/766566, 10/768293, 10/791915 and 10/775586 are maintained.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-17 have been fully considered but they are not persuasive.

Applicant argues that Howell et al do not "disclose or suggest depositing a drug on a substrate, as required by Claim 1 of the present application". This is not persuasive because Howell et al teaches placing the drug in a tube, and it is considered that a "tube" reads on "a substrate". Instant claims do not specify any form for the drug, thus Howell's "liquid" also reads on the instant "drug".

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Applicant argues that Howell et al disclose particles of less than 2 micron and do not "teach one of ordinary skill in the art how to prepare an aerosol with a mass median aerodynamic diameter of less than 0.1 micron". This is not persuasive because a disclosure of "less than 2 microns" encompasses "less than 0.1 micron". Howell et al discloses various formulations with different particle size in tables II and III. The sizes of 0.37 micron have been disclosed. Weidemann teaches that nanoparticles of less than 400 nm and less than 100 nm are suitable for pulmonary delivery. It is also noted that optimization of ranges is a) obvious to one of ordinary skill in the art and b) NOT a support for patentability.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian  
June 20, 2006

  
JOHANN RICHTER  
SUPERVISORY PATENT EXAMINER  
GROUP 1200